Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of High-Power Static Ultrasound Combined with Dry Cupping Therapy on Pain Level and Functions in Patients with Myofascial Trigger Points in Trapezius: A Comparative Study

Protocol summary

Study aim

Assess the effects of dry cupping therapy combined with high power static ultrasound compared to dry cupping alone and standard medical care (SMC) in patients with myofascial pain syndrome in trapezius to find out the most effective protocol in reducing pain, increasing range of motion, improving function and limiting disabilities of patients with Myofascial Trigger points in trapezius.

Design

Single Blinded RCT, 45 participants, 3 groups (15 in each one), 8 sessions for 4 weeks, 3 times assessments T1 T4 T8.

Settings and conduct

Blinding data analyser. The outcomes of specific group are blinded from the data analyser.

Participants/Inclusion and exclusion criteria

Inclusion Criteria - Patients diagnosed with chronic nonspecific neck pain following palpable trigger points for more than 3 months. - Age 25-50 years from both genders. - Patients with neck pain that is scored 30 mm out of 100 mm or greater on the VAS during activity. - Presenting unilateral (or bilateral) trapezius myofascial trigger points (3 to 6) for more than 3 months with an intensity disturbing normal daily activity. Exclusion criteria - Systemic disorder or migraine; - Patients on medication for trigger points or physiotherapy treatment in the previous 3 weeks prior to the study; - Pregnant women; - Have had any trauma to the neck in the last 6 months; - Skin Inflammation; - Skin Lesion; - Open Wounds - Patients who refused to continue the study.

Intervention groups

1) Group A: High power static ultrasound + dry cupping + standard medical care 2) Group B: Dry cupping + standard medical care 3) Group C: standard medical care

Main outcome variables

Pain at rest and at movement (VAS), range of motion (universal goniometer), functional capacity (FCE), neck disability (NDI).

General information

Reason for update

Acronym

MPS (Myofascial Pain Syndrome)

IRCT registration information

IRCT registration number: **IRCT20230205057325N1**
Registration date: **2023-03-15, 1401/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-15, 1401/12/24**
Update count: **0**

Registration date

2023-03-15, 1401/12/24

Registrant information

Name

Nassab Toufayli

Name of organization / entity

Country

Lebanon

Phone

+961 71 545 368

Email address

nassabtoufayli@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-25, 1401/12/06

Expected recruitment end date

2023-03-30, 1402/01/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of High-Power Static Ultrasound Combined with Dry Cupping Therapy on Pain Level and Functions in Patients with Myofascial Trigger Points in Trapezius: A Comparative Study

Public title
Effects of Dry Cupping with Ultrasound in treatment of Chronic Neck Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with chronic nonspecific neck pain following palpable trigger points for more than 3 months. Age 25-50 years from both genders. Patients with neck pain that is scored 30 mm out of 100 mm or greater on the VAS during activity. Presenting unilateral (or bilateral) trapezius myofascial trigger points (3 to 6) for more than 3 months with an intensity disturbing normal daily activity.
Exclusion criteria:
Systemic disorder or migraine Patients on medication for trigger points or physiotherapy treatment in the previous 3 weeks prior to the study Pregnant women Have had any trauma to the neck in the last 6 months Skin Inflammation Skin Lesion Open Wounds Patients who refused to continue the study.
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Each participant has the opportunity to choose the intervention group randomly by pick up a small paper on which the name of the intervention will be written.
Blinding (investigator's opinion)
Single blinded
Blinding description
the data analyser will be blinded from the specific results of each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the Faculty of Nursing and Midwifery and the Faculty of Rehabilitation - Tehran
Street address
Quds town (west), between South Flamek and Zarafshan, Simai Iran St., Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor
City
Tehran
Province
Tehran
Postal code
0000
Approval date
2023-02-19, 1401/11/30
Ethics committee reference number
IR.TUMS.FNM.REC.1401.181.

Health conditions studied

1

Description of health condition studied
Chronic Neck Pain for more than 3 months.
ICD-10 code
neck pain
ICD-10 code description
neck pain, myofascial pain syndrome, dry cupping, high power static ultrasound, trigger points

Primary outcomes

1

Description
pain at rest
Timepoint
before intervention, after 2 weeks and after intervention (after 4 weeks)
Method of measurement
Visual Analogue Scale

2

Description
pain at movement
Timepoint
before intervention, after 2 weeks and after intervention (after 4 weeks)
Method of measurement
Visual Analogue Scale

3

Description
range of motion
Timepoint
before intervention, after 2 weeks and after intervention (after 4 weeks)
Method of measurement
universal goniometer

4

Description
functional capacity
Timepoint
before intervention, after 2 weeks and after intervention (after 4 weeks)
Method of measurement
Functional Capacity Evaluation

Secondary outcomes

1

Description
neck disability
Timepoint
before intervention, after 2 weeks and after intervention (after 4 weeks)
Method of measurement
Neck Disability Index

Intervention groups

1

Description
Intervention group 1: high power static ultrasound + dry cupping + standard medical care. High power static ultrasound technique will be applied according to the following settings: 1 MHz frequency, 1.5 W/cm2 intensity, for 2 minutes on each point (Less than 10 points). Standard medical care including 7 minutes of superficial heat (hot pack) at a temperature of 65.5 °C, 20 minutes of pulsed mode TENS with a duration of 100–110 µs, and a frequency of 70–80 Hz, symmetrical with 4 electrodes and Upper trapezius stretching exercises.
Category
Rehabilitation

2

Description
Intervention group 2: Dry cupping, plastic cups with medium power of suction will be applied on injured area by 4-10 glasses with sizes of cup 25 to 50 mm, 10 to 15 min on the trigger points for each cup.
Category
Rehabilitation

3

Description
Control group: Standard medical care including 7 minutes of superficial heat (hot pack) at a temperature of 65.5 °C, 20 minutes of pulsed mode TENS with a duration of 100–110 µs, and a frequency of 70–80 Hz, symmetrical with 4 electrodes and Upper trapezius stretching exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
NASSAB Physio Center
Full name of responsible person
Nassab Ibrahim Toufayli
Street address
AL SULTAN Street
City
Beirut Nabatieh
Postal code
no one
Phone
+961 71 545 368
Email
nassabtoufayli@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nassab Ibrahim Toufayli
Street address
Ras el Nabeh, shokeir blvd
City
Beirut Nabatieh
Postal code
no one
Phone
+961 71 545 368
Email
nassabtoufayli@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Nassab Physio Center
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nassab Ibrahim Toufayli

Position

student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Ras al nabeh, shokeir Blvd

City

Beirut Nabatieh

Province

Beirut

Postal code

no one

Phone

+961 71 545 368

Email

nassabtoufayli@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

dr Siamak Bashardoust Tajali

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Tehran

City

Tehran

Province

Tehran

Postal code

no one

Phone

+98 912 107 9244

Email

s_bashardoust@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nassab Ibrahim Toufayli

Position

student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Ras el Nabe, shokeir blvd

City

Beirut Nabatieh

Province

Beirut

Postal code

no one

Phone

+961 71 545 368

Email

nassabtoufayli@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data for admission; Demographics details (age (25-50), weight, height), VAS> 30mm with activity at baseline, Patients diagnosed with chronic nonspecific neck pain following palpable trigger points for more than 3 months, Presenting unilateral (or bilateral) trapezius myofascial trigger points (3 to 6) for more than 3 months with an intensity disturbing normal daily activity. Sampling The sample size was measured using the “G-power” 3.1.9.4 version available software by taking into consideration the mean and standard deviation of previous published data. Then, 15 participants were specified as the sample of each group. Myofascial trigger point will be confirmed by the following diagnostic criteria: Primary criteria (all 5 are needed): 1. Regional pain complaint. 2. Pain complaint or altered sensation in the expected distribution of referred pain from a trigger point. 3. Taut band palpable in an accessible muscle 4. Exquisite spot tenderness at 1 point along the length of the taut band.

5. Some degree (20 to 60 degrees) of restricted range of motion. Secondary criteria (1 of 3 is needed): 1. Reproduction of clinical pain complaint, or altered sensation, by pressure on the tender spot. 2. Local twitch response elicited by snapping palpation at the tender spot or by needle insertion into the tender spot. 3. Pain alleviated by elongating (stretching) the muscle or by injecting the tender spot. Method of assignment to study groups The simple random sampling technique will be used to distribute 45 participants into groups of intervention; each participant has the opportunity to choose the intervention group randomly by pick up a small paper on which the name of the intervention will be written. Procedure of Intervention: The participants will be randomly allocated into three groups: 1) Group A: High power static ultrasound + dry cupping + standard medical care 2) Group B: Dry cupping + standard medical care 3) Group C: standard medical care Each protocol of intervention consists of 8 sessions over 4 weeks (2 sessions per week). All participants will receive standard medical care including 7 minutes of superficial heat (hot pack) at a temperature of 65.5 °C, 20 minutes of pulsed mode TENS with a duration of 100–110 µs, and a frequency of 70–80 Hz, symmetrical with 4 electrodes and Upper trapezius stretching exercises. Additionally, the High power static ultrasound technique will be applied according to the following settings: 1 MHz frequency, 1.5 W/cm2 intensity, for 2 minutes on each point (Less than 10 points). And Dry cupping, plastic cups with medium power of suction will be applied on injured area by 4-10 glasses with sizes of cup 25 to 50 mm, 10 to 15 min on the trigger points for each cup. It's worth mention that the participants were asked not to take analgesics or non- steroid anti-inflammatory drugs (NSAIDs) to avoid the analgesic effects of these drugs throughout the study period. Data Analysis The SPSS version 26 will be used. The normality of the data will be assessed using the Kolmogorov-Smirnov test, then it would be confirmed by using the one-way ANOVA test at baseline to check any significant difference between participants before the intervention. After that, if the data was normally distributed, the repeated measures ANOVA will be used to compare between groups and the paired sample t-test will be used to assess the significance of the improvement after the intervention. If the data was not normally distributed, the Wilcoxon test and the Mann-Whitney U test will be used. It's worth noting that the level of significance will be considered at $p<0.05$ with an interval of confidence of 95%. Moreover, the descriptive analysis will be based on mean and standard deviations of the demographic variables of the participants.

When the data will become available and for how long

June 2023

To whom data/document is available

Dr. Siamak Bashardoust

Under which criteria data/document could be used

it is not yet decided

From where data/document is obtainable

It is not yet decided

What processes are involved for a request to access data/document

Inviting by Social Media

Comments